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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/383,745 08/26/99 GLUCKSMANN

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EXAMINER

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ART UNIT

PAPER NUMBER

1646

DATE MAILED:

07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/383,745

Applicant
Glucksmann

Examiner
Eliane Lazar-Wesley

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 18, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19 and 21-31 is/are pending in the application.
- 4a) Of the above, claim(s) 17, 18, and 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19 and 21-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5,6 20) ☐ Other:

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DETAILED ACTION

1. The amendment filed June 18, 2001, has been entered.
2. Claims 17-19, 21-22, and new claims 23-31, are pending. Claims 19 and 21 have been amended.
3. Applicant's election with traverse, in Paper #10 filed June 18, 2001, of Group VII, drawn to methods of modulating the activity of a polypeptide using a compound, is acknowledged. The traversal is on the grounds that Group VI, directed to a method of identifying a binding partner, should be examined with Group VII. This is not found persuasive for the reasons of record, and because the methods of Groups VI and VII are different in their mode of operation, and require different method steps and reagents, and measure different compounds or reactions. For example, the method of Group VI could be quantified with an antibody against the polypeptide or the binding partner, while the methods of Group VII requires to measure the biological activity of the polypeptide. The searches for the various groups are different, as they require references that anticipate the invention as well as to references that render the invention obvious, and therefore require a search of relevant literature in many areas of subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Claims 28-31, that apply to the method of Group VI, are withdrawn from consideration as being non-elected.

Claims 19 and 21-27 that apply to the method of Group VII, are under consideration..

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Claim Rejections - 35 USC § 101/112

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 19 and 21-27 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claims are to methods of modulating the activity of a polypeptide of SEQ ID No:1 or variants thereof, using a compound

Applicants disclose the nucleic acid and deduced amino acid sequence of a "14926 receptor", that they describe as being a G-protein coupled receptor (GPCR), based upon structural motifs characteristic of other GPCR, or a hydrophobicity plot (Figures 2 and 4, for example). Applicants do not provide a specific utility for the claimed "14926 receptor", as for example no ligand for the receptor, no specific function for the receptor, and no specific and substantial signaling activity or cellular response are disclosed. The gene and the protein of the invention are disclosed, page 3, lines 28-31, as being useful as targets and reagents in receptor assays applicable to treatment and diagnostic of (yet undefined) GPCR-mediated disorders. However, this constitutes an invitation to

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experiment and an invitation to use the gene and encoded protein as a research tool, but does not provide at the present time a specific and well established utility. We are in the situation of testing a receptor of unknown function with an unknown ligand, and of using the recepto as a research tool for finding a ligand and finding out which signaling or response are triggered by activation, or which disease is involved in the activation of the potential receptor. Applicants do not provide a specific and well established utility providing patentability for their invention. The invention therefore does not fulfill the requirements of 35 USC 101.

7. Claims 19 and 21-27 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention and which activity to measure.

8. Claims 19 and 21-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 19 and 25 recite in parts c, d, e and f, allelic variants and sequence variants of the amino acid of SEQ ID No:1. Applicants do not disclose such variants, nor do they teach which parts

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of the polypeptide of SEQ ID No:1 is essential for the activity of the polypeptide, or which mutations in the polypeptide will be tolerated for maintaining the function.

Furthermore, applicants claim a method wherein the polypeptide is contacted with "an agent"(claim 19) or "a test compound"(claim 25). Applicants do not disclose that they are in possession of such an agent or compound, or what the necessary structural or chemical characteristics of such an agent are.

Applicants do not convey that they were in possession of the invention at the time of filing.

9. Claims 19 and 21-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record.

Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. When biological material is required to practice an invention, and if it is not so obtainable or available, the enablement requirements of 35 USC '112, first paragraph, may be satisfied by a deposit of the material. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the cDNA contained in ATCC Deposit No ?, and it does not appear to be a readily available material. Deposit of the ATCC clone would satisfy the requirements of 35 USC '112, first paragraph.

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If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;
- (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- (d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that *"the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination."*

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10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19 and 21-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 and 25, and their dependent claims, are indefinite and incomplete, as they do not recite the number under which the clone has been deposited at ATCC.

Claim 19 is incomplete, as the method steps do not refer back to the preamble.

Claims 19 and 25, and their dependent claims are indefinite, as they recite "the activity of the polypeptide", without defining what this activity is.

Claims 19 and 25 recite "an agent" or "a compound", without providing the structural or physical characteristics of the agent or the compound.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Elshourbagy et al., US Patent 6,071,722, teach the nucleic acid and amino acid sequence of a G-protein coupled 7TM receptor. The amino acid sequence of '722 is 100% identical over its

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entire length to the instant SEQ ID No:1 (see sequence comparison, attached). He does not teach the method or the compounds.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

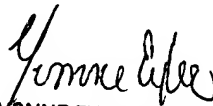
Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

June 29, 2001

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YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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